UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

JUL 20 2009

REPLY TO THE ATTENTION OF:

AE-17J

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Stephen Morris
Director, Environmental Health and Safety
Sterigenics International, Inc.
2015 Spring Road, Suite 650
Oak Brook, Illinois 60523

Re: Proposed Monitoring Plans for Willowbrook I and II

Dear Mr. Morris:

Thank you for your letters dated February 23, 2009 and March 25, 2009 and related electronic mail, to the U.S. Environmental Protection Agency, requesting EPA approval of alternative monitoring plans for the Advanced Air Technologies ("AAT") Dry Bed Reactor systems at Sterigenics International, Inc.'s ("Sterigenics") Willowbrook I and II facilities located in Willowbrook, Illinois. Sterigenics is an ethylene oxide sterilizer headquartered in Oak Brook, Illinois. The company owns and operates a number of facilities world-wide that sterilize medical and food products. Two such facilities are Willowbrook I, located at 7775 South Quincy Street in Willowbrook, Illinois and Willowbrook II, located on property contiguous to Willowbrook I at 830 Midway Drive, Willowbrook, Illinois. This combined facility is subject to the National Emission Standards for Hazardous Air Pollutants ("NESHAP") for Commercial Ethylene Oxide Sterilization Operations, 40 CFR Part 63, Subpart O ("Ethylene Oxide NESHAP"). The most recent revised monitoring plans for Willowbrook I and II, dated June 22, 2009, were submitted electronically on June 23, 2009.

The purpose of this letter is to notify you of our intent, pursuant to 40 CFR § 63.8(f)(5)(i), to disapprove both Willowbrook I and II monitoring plans and to provide you with an opportunity to submit additional information prior to such disapproval. The information and findings that are the basis of our intent to disapprove the plans are detailed below.

Background

Sterigenics is subject to the ethylene oxide emission standards in 40 CFR § 63.362(c) and (d). 40 CFR § 63.362(c) requires an owner or operator of a sterilization source using 1 ton to reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent. 40 CFR § 63.352(d) requires each owner or operator of a sterilization source using 10 tons to reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.

At Willowbrook I, emissions from the aeration room vents are sent to the AAT Scrubber ("SC-1") and Dry Bed Reactor ("SC-2"), operated in series. Emissions from the sterilization chamber vents are sent to a DEOXX Scrubber and then only to the AAT Scrubber and Dry Bed Reactor System, SC-1 and SC-2, in the event of a malfunction of the DEOXX system. Emissions from the sterilization chamber vents are never sent to the Dry Bed Reactor, SC-2, alone. At Willowbrook II, both sterilization chamber vent emissions and aeration room vent emissions are sent to a different SC-1 and SC-2 system, operating in series at that facility.

Sterigenics is requesting U.S. EPA's approval to use the AAT Dry Bed Reactor, SC-2, instead of using the AAT Scrubber with Dry Bed Reactor ("SC-1 and SC-2") for controlling ethylene oxide emissions from the aeration rooms at both Willowbrook 1 and II. (Emissions from the sterilization chamber vents are not sent to the dry beds alone). This change will only be implemented when the AAT Scrubber, SC-1, is either inoperable or undergoing maintenance. Sterigenics is requesting this change so that they will be able to service the AAT Scrubber while still operating the aeration rooms. The U.S. EPA approval will allow Sterigenics to continue to aerate medical devices and spices whenever there is a scrubber breakdown or need to conduct maintenance on the scrubber.

On December 19, 2002, EPA approved Sterigenics original alternative monitoring plans for the control systems at Willowbrook I and II. At the time these plans were approved, Sterigenics operated the AAT Scrubbers, SC-1, followed by the AAT Dry Bed Reactors, SC-2 in series. The dry bed reactor systems were never used alone. The 2002 plan requires Sterigenics to conduct measurements on a weekly basis for the concentration of ethylene oxide in the exhaust from each Dry Bed Reactor, SC-2. EPA also approved performance specifications and quality assurance procedures for the monitors contained in the following documents: "Performance Standards for Tiered Monitoring Plan for Willowbrook I and II Facilities" and "Facility Work Instructions: Environmental and Monitoring Equipment Malfunction and Monitoring Plan for Tiered Monitoring Program" both received December 6, 2002. Prior to submitting the December 2002 monitoring plans for approval, Sterigenics had submitted performance testing showing that SC-1 and SC-2 together in series demonstrated compliance with the aeration room vent standard. After approval of the monitoring plans, Sterigenics again conducted performance testing with the monitoring systems in place.

Regulatory Background

The Ethylene Oxide NESHAP requires the establishment of site-specific monitoring parameters for emission control equipment to verify that a control device is operating in continuous compliance. The NESHAP provides specific requirements for what parameters should be monitored when either wet scrubbers or catalytic oxidizers are used for control. However, when a facility is complying with the emission limits of 40 CFR § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator of the facility must provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating parameter(s) to be measured during the performance test. During the performance test required by 40 CFR § 63.363(a), using the methods approved in § 63.365(g), the owner or operator must determine the site-specific operating limit(s) for the operating parameters approved by the Administrator.

40 CFR § 63.365(g) requires an owner or operator of a sterilization facility seeking to demonstrate compliance with the standards found at 40 CFR § 63.362(c), (d), or (e) with a control device other than an acid-water scrubber or catalytic or thermal oxidization unit to provide to the Administrator the information requested under 40 CFR § 63.363(f) to demonstrate continuous compliance. The owner or operator must submit: a description of the device; test results collected in accordance with 40 CFR § 63.363(f) verifying the performance of the device for controlling ethylene oxide emissions to the atmosphere to the levels required by the applicable standards; the appropriate operating parameters that will be monitored; and the frequency of measuring and recording to establish continuous compliance with the standards. The monitoring plan submitted identifying the compliance monitoring is subject to the Administrator's approval. The owner or operator of the sterilization facility must install, calibrate, operate and maintain the monitor(s) approved by the Administrator based on the information submitted by the owner or operator. The owner or operator shall include in the information submitted to the Administrator proposed performance specifications and quality assurance procedures for their monitors. The Administrator may request further information and shall approve appropriate test methods and procedures.

Sterigenics Current Proposed Monitoring Plans for Willowbrook I and II

Since February 2009, when Sterigenics first submitted proposed monitoring plans for the dry bed reactors for approval by EPA, conversations have occurred between you and Ms. Linda H. Rosen, of my staff, regarding the monitoring plans. As a result of these discussions, changes were made to the February 23, 2009 proposed plans and revised proposed monitoring plans, dated June 22, 2009, were submitted via electronic mail on June 23, 2009. These are the plans that are the subject of this letter.

The June 22, 2009 proposed plans contain changes to the 2002 approved monitoring plans to allow for the use of the AAT Dry Bed Reactor, SC-2, instead of using the AAT Scrubber with the Dry Bed Reactor, SC1 and SC2, for controlling ethylene oxide emissions from the aeration room vents for both Willowbrook I and II. This change will only be implemented when SC-1 is either inoperable or undergoing maintenance. The plans require that, at both Willowbrook I and II, when SC-1 and SC-2 are operating in series, the SC-2 dry bed reactors inlet and outlet will be sampled once per week utilizing gas bags. The gas samples of the exhaust from the dry bed inlet and outlet will be collected for a minimum of 15 minutes using a modified Method 18 (only one 15 minute bag sample for both the inlet and outlet). A Perkin Elmer gas chromatograph ("GC") will be utilized to determine the ethylene oxide concentration level at the inlet and outlet. The testing will occur when there is product aerating in the aeration rooms. Should there be three consecutive weeks where outlet average ethylene oxide readings of greater than 0.90 ppm occur, then the dry bed material will be changed out completely within 7 days after the third consecutive weeks test.[1] If the scrubber SC-1 goes down at either facility, then daily ethylene oxide concentration monitoring will occur beginning after the first 24 hours. Should there be three consecutive days where outlet average ethylene oxide readings of greater than 0.90 ppm occur, then the dry bed material will be changed out completely within 120 hours of the third consecutive day's testing results that are above 0.90 ppm. If the DEOXX scrubber malfunctions at Willowbrook I, and sterilization chamber vent emissions are sent to SC-1 and SC-2, then currently weekly monitoring is required and a limit of 60 ppm ethylene oxide concentration is specified at the outlet. When sterilization chamber vent emissions are sent to SC1 and SC2 at Willowbrook II, then currently weekly monitoring is required and 60 ppm ethylene oxide is the limit at the outlet.

The revised plans appear to incorporate the same or nearly the same performance specifications and quality assurance procedures as those in 2002 except that, instead of using the Foxboro Century OVA, the Thermo Environmental Systems TVA-1000B Toxic Vapor Analyzer, the Baseline GC PID 8550 Ethylene Oxide Monitor, and one Perkin Elmer Model 5216 Ethylene Oxide FID monitor, the facility now uses two Perkin Elmer Model 5216 Ethylene Oxide FID monitors. One is located at each facility but they can be used interchangeably if one goes down.

The plans along with the supporting documents submitted by Sterigenics include descriptions of the Dry Bed Reactors SC-2, the parameters to be monitored, the frequency of measuring and recording the parameters, 2003 performance test results, and proposed performance specifications and quality assurance procedures (contained in the "Performance Standards For Sterigenics Monitoring Plans" and "Facility Work Instructions", both submitted with the February 23, 2009 letter.

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1 The June 22, 2009 monitoring plans specify a limit of 0.9 ppm or less. On July 14, 2009, you told Ms. Linda H. Rosen, during a telephone call that the instrumentation can determine the ethylene oxide concentration to the hundredth place so that the limit is now 0.90 or less, not 0.9 ppm.

EPA's Determination

Sterigenics has not yet conducted testing in accordance with 40 CFR § 63.363(f), verifying the performance of the Dry Bed Reactor, SC-2, only at each facility for controlling ethylene oxide emissions to the atmosphere to the levels required by the applicable standards. Although Sterigenics conducted three test runs each at Willowbrook I and II in 2003 during which simultaneous inlet and outlet measurements were taken at the dry beds, these runs were conducted while emissions were first being treated by the scrubbers. This situation is not representative of what would occur if the scrubbers are bypassed. You must conduct performance testing while both the AAT Scrubber, SC-1, and AAT Dry Bed Reactor, SC-2, are operating at each facility AND while ONLY the AAT Dry Bed Reactors are operating at each facility to ensure compliance in both scenarios. To verify that the dry beds can operate in compliance by themselves, you must conduct testing with aeration room vent emissions bypassing the scrubbers. Further, since there may be occasions when the sterilization chamber exhaust emissions are vented to the SC-1 and SC-2 system, both at Willowbrook 1 and II, Sterigencis should conduct testing when emissions from both chambers and aeration rooms are vented to the SC-1 and SC-2 system. The details of the testing and the different operating scenarios should be addressed in the proposed test protocol.

Based on the information submitted to date, EPA approves the proposed operating parameters that will be monitored during the performance test (scrubber liquor level for the DEOXX and SC-1 scrubbers, and ethylene oxide concentration for the SC-1 and SC-2 systems and the SC-2 system alone). Subject to the performance testing described above that needs to be conducted and demonstrate compliance with the standard during all operating scenarios, EPA conditionally approves the frequency of monitoring of the ethylene oxide concentration (weekly when SC-1 and SC-2 are both operating in series and daily after the first 24 hours when only SC-2 is operating). EPA also conditionally approves the 0.90 ethylene oxide concentration value as an operating limit that will also trigger changeout of the dry beds when only the aeration room vent emissions are going to the dry beds. We currently do not see a problem with your modified Method 18 sampling method, previously approved in 2002, of one 15-minute bag sample at both the inlet and outlet of the dry beds rather than three samples. Regarding the performance specifications and quality assurance procedures, EPA is still unclear as to how and why your proposed performance specifications and quality assurance procedures do not meet all the requirements of 40 CFR § 63.6, and Performance Specifications 8 and 2. Please submit information indicating that your proposed monitoring plans meet the requirements of 40 CFR § 63.6 and Performance Specifications 8 and 2 or clearly delineate how and why the procedures and specifications do not meet the requirements (e.g., calibration drift). Your proposed calibration procedures should be discussed in the monitoring plans at the level of detail similar to that found in your Smyrna, Georgia facility monitoring plan. EPA does not have any issues with the use of two Elmer Model 5216 Ethylene Oxide FID monitors.

EPA has the following other comments and questions about the monitoring plan. Please submit answers to these questions, and those above, plus any additional information when you submit your revised plans. Some of these questions were posed to you during a recent phone conversation and we understand that you are gathering the information. If you wish to discuss any of these issues prior to conducting testing or submitting revised monitoring plans, we would be happy to do so.

(1) It is not clear which monitoring plan belongs to which facility based on the cover pages and references within the documents. Please correct this.
(2) Willowbrook I's monitoring plan needs to address the situation when the sterilization chamber vent emissions are sent to the SC1 and SC2 system. This situation is not addressed in what appears to be the monitoring plan for Willowbrook I.
(3) It is not clear how the 60 ppm threshold was determined for monitoring purposes when the chamber emissions are vented to the SC1 and SC2 system at Willowbrook II. Please explain this. This outlet concentration limit value should be based on performance test results. It is not clear how the 60 ppm limit ensures compliance throughout the full range of incoming ethylene oxide concentration values.
(4) Regarding the DEOXX and SC-1 acid scrubbers, you have chosen the scrubber liquor level in the acid-water scrubber recirculation tank as the operating parameter to be monitored. This is acceptable to EPA. However, EPA does not see where you state the monitoring frequency in the monitoring plan (it should be weekly per the regulation). You specify a maximum scrubber liquor level of 159 inches based on 2000 performance testing. This level should be revised based on the new testing to be conducted and you must follow the procedures in 40 CFR § 63.365(e) to establish such limit. You do not describe what type of liquid level indicator will be used to measure the scrubber liquor level. Please add the information in this paragraph to the monitoring plan.
(5) You and Ms. Linda H. Rosen, of my staff, discussed the possibility of increasing the monitoring frequency to daily (after the first 24 hours) when the sterilization chamber exhaust emissions are being vented to the SC-1 and SC-2 system. This situation would occur when the DEOXX scrubber is down at Willowbrook I and when sterilization occurs at Willowbrook II. The reason for this is that sterilization chamber vent emissions will significantly increase the load to the dry beds even though the SC-1 scrubbers are in operation. Please address the value, if any, of daily monitoring in these situations in your proposed revised monitoring plans or in a supplementary letter. It is not clear to EPA the percentage of time that sterilization chamber vent emissions are sent to the SC1 and SC2 system at Willowbrook II.
(6) Both monitoring plans discuss how ethylene oxide usage relates to the useful life of the dry beds. Your calculations do not address the situation when the scrubber, SC-1, is down. The calculations should include an assessment of how fast the beds would be used up if SC-1 is down and during the various operating scenarios.
(7) You must address a potential non-compliance issue relative to the sterilization chamber vents. At Willowbrook I there is the potential for sterilization to be in process

when the DEOXX scrubber and SC-1 goes down. At Willowbrook II, there is the potential for sterilization to be in process when SC-1 goes down. EPA's understanding is that in these situations, the sterilization process stops, the vacuum pumps shut down, and no additional ethylene oxide gas is added to the chambers. However, there still could be a large quantity of ethylene oxide gas already in the chambers that must be controlled. Since you are not, by permit, allowed to send chamber exhaust emissions to the dry beds, you must address how you will meet the chamber emission standard (99 percent control) when the DEOXX scrubber and SC-1 go down at Willowbrook I and when SC-1 goes down at Willowbrook II. EPA does not see that the NESHAP allows Sterigenics to vent sterilization chamber emissions to the atmosphere when these control devices go down. Sterigenics must also specify that it will not intentionally shut down the SC-1 scrubbers (such as for maintenance) when sterilization is occurring.

(8) In the "Facility Work Instructions," you indicate that there may be times when there is not sufficient standard ethylene oxide gas available for calibrating the Perkin Elmer GCs. The "Facility Work Instructions" should contain procedures to ensure that there will always be ethylene oxide standard gas available at the facility in the right concentrations and before the stated expiration date for the necessary calibrations. The plan should specify what concentration of standard gas will be used for calibrations.

(9) The "Facility Work Instructions" and "Performance Standards for Sterigenics Monitoring Plans" need to be updated to reflect the increased monitoring that will be occurring (daily) when the SC-1 scrubbers go down.

EPA's understanding is that Sterigenics is in the process of constructing the necessary ductwork so that aeration room emissions can bypass the scrubber. When this process is complete, Sterigenics must conduct testing under a protocol approved by both EPA and IEPA. The protocol must include a proposal for how monitoring will be conducted during testing to gather the necessary data to verify that the proposed monitoring plans will ensure continuous compliance with the standards. Sterigenics should submit the test results and proposed monitoring plans, along with the additional information requested, to EPA as one package for approval.

If you have any questions about this letter, please feel free to contact Linda H. Rosen, of my staff, at (312) 886-6810.

Sincerely,

for George T. Czerniak
Chief
Air Enforcement and Compliance Assurance Branch

cc: Ray Pilapil, Manager
Bureau of Air – Compliance and Enforcement Section
Illinois Environmental Protection Agency